



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,054	03/10/2000	Shyam S. Mohapatra	0152.00355	4567

7590

06/07/2002

Kenneth I Kohn
Kohn and Associates
Suite 410
30500 Northwestern Highway
Farmington Hills, MI 48334

EXAMINER

SCHEINER, LAURIE A

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 06/07/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/523,054

Applicant(s)
Mohapatra et al.

Examiner
Laurie Scheiner

Art Unit
1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 4, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 7-9 and 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 6) ☐ Other:

Art Unit: 1648

Claims 1-18 are pending in this application. Claims 7-9 and 13-18 are withdrawn from consideration as being drawn to a non-elected invention. Applicant's election of Group I, claims 1-6 and 9-12, in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). That is, efficiency of examination is not an appropriate argument against the restriction requirement since the basis for the requirement has to do with a common utility and corresponding structures. Respective searches would neither be co-extensive nor efficient since there is no common structural feature essential and central to the utility of the invention. Again, applicants fail to directly address the examiner's reason for requiring the election.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preventing RSV infection, does not reasonably provide enablement for a method whereby any respiratory infection is prevented. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. That is, ICAM-1 does not serve as a cell membrane receptor for all viruses, bacteria, and environmental factors which may cause respiratory infections. It is asserted that ICAM-1 is generally accepted as a cell membrane receptor for respiratory viruses (rhinovirus, parainfluenza virus, etc). Also, if the

Art Unit: 1648

"respiratory infection" agent was other than a respiratory virus, the claims would be improperly set forth since the infection *per se* would not be prevented by the instant method even though (mechanism dependent) the subsequent inflammation may be blocked. The specification also fails to enable the administration of agent orally or by inhalation since the mode of administration is agent dependent. That is, the agent is unknown.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3 and 10-12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Patel. et al. (American Journal of Respiratory Cell and Molecular Biology, (1995) Vol. 13, No. 5, pp. 602-609).

Patel et al. teach that respiratory epithelial cells are the primary target cell for RSV infection and produce proinflammatory and immunoregulatory cytokines and express adhesion molecules, suggesting that the respiratory epithelial cell may be the most important cell to regulate the initial stages of inflammation and host immune responses in the microenvironment of the respiratory mucosa. Thus, it is suggested that the clinical use of an ICAM-1 inhibitor may lead to the reduction of disease severity due to RSV infection. More specifically, Patel et al. teach that simultaneous incubation of infectious purified RSV with sIL-1r resulted in a significant reduction in enhancement of ICAM-1 expression.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kumasaka et al. (J. Clin. Invest. 97:2362-2369, 1996).

Art Unit: 1648

Kumasaka et al. teach that anti-sense oligonucleotides inhibited upregulation of ICAM-1 expression induced by intratracheal instillation of endotoxin into the distal airway, subsequently preventing the acute inflammatory response.

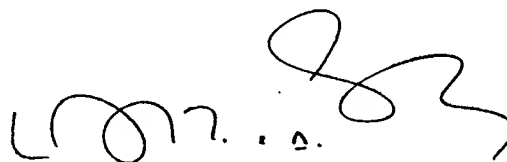
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.



Laurie Scheiner/LAS
May 29, 2002



LAURIE SCHEINER
PRIMARY EXAMINER